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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/775,888	02/10/2004	Rainer Endermann	Le A 36 499	1423
35969 7590 12/11/2007 JEFFREY M. GREENMAN BAYER PHARMACEUTICALS CORPORATION 400 MORGAN LANE WEST HAVEN, CT 06516			EXAMINER WANG, SHENGJUN	
			ART UNIT 1617	PAPER NUMBER
			MAIL DATE 12/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/775,888	Applicant(s) ENDERMANN ET AL.	
	Examiner Shengjun Wang	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 6-14 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 6-8 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made **without** traverse in the reply filed on October 16, 2007.

2. Applicant's election without traverse of invention group I, in the reply filed on October 16, 2007 is acknowledged.

Claim Rejections 35 U.S.C. 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 2 and 14 are rejected under 35 U.S.C. 102(e) as being anticipated by Pikiewicz et al. (US 2004/0009126 A1).

5. Pikiewicz et al. teach a method of treating bacterial lung infection comprising locally administration of ciprofloxacin by inhalation, wherein the ciprofloxacin is in the form of particle and may be in the form of dry powder. See, particularly, the abstract, paragraphs [0064] and [0069], and the claims.

Claim Rejections 35 U.S.C. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 1, 2 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. in view of Li et al.

Mayer et al. treated anthrax lung infection by administering to the patients ciprofloxacin. The administration is carried out intravenously. See, particularly, the abstract, pages 2550 and 2551. Mayer et al. further disclosed that it is well known that ciprofloxacin is effective against anthrax and is a standard treatment of anthrax. See, page 252, the right column.

Mayer et al. do not teach expressly local administration as herein claimed.

However, Li et al. teach ciprofloxacin administration intravenously or orally have relatively unfavorable pharmacokinetic profile in the lower respiratory track. Li also disclosed that Aerosol inhalation as means of drug delivery to the respiratory tract has been well established in the treatment of lung disease, and dry powder inhaler have received increasing attention in the art. Li et al. further teaches a ciprofloxacin loaded particles for dry powder inhaler delivery to the respiratory track by inhalation. See, particularly, the abstract and introduction at page 825.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use dry powder inhaler for delivery ciprofloxacin composition, such as those disclosed by Li, directly to respiratory track for treatment of respiratory track bacterial infection, such as anthrax infection.

A person of ordinary skill in the art would have been motivated to use dry powder inhaler for delivery ciprofloxacin composition, such as those disclosed by Li, directly to respiratory

track for treatment of respiratory track bacterial infection, such as anthrax infection because the delivery method is more effective than intravenous or oral delivery.

8. Claims 3, 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mayer et al. in view of Li et al. for reasons set forth above, and further in view of Grohe et al. (US 4,670,444, IDS), and Vetter et al. (US 5,808,076).

9. Mayer and Li as whole do not teach expressly the embonate salts of ciprofloxacin.

10. However, Grohe et al. disclose ciprofloxacin or its acid additional salts are similarly useful as antibacterial agents against a wider spectrum of gram positive and gram-negative bacteria. See, columns 10-11 and the claims. Vetter et al. teaches that incorporating embonic acid with ciprofloxacin or enrofloxacin with mask the bitterness of ciprofloxacin and enrofloxacin.

11. Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make a acid added ciprofloxacin salt with embonic acid and use it for dry powder inhalation delivery.

12. A person of ordinary skill in the art would have been motivated to make a acid added ciprofloxacin salt with embonic acid and use it for dry powder inhalation delivery because it is known acid additive salts of ciprofloxacin are known to be similarly useful as ciprofloxacin and embonic acid is particularly known to provide benefit for masking the bitterness of ciprofloxacin. Further, making an acid addition salt of an organic compound is within the purview of skilled artisan.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

Application/Control Number:
10/775,888
Art Unit: 1617

Page 5

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617